Study backs ImClone drug's effectiveness

POSTED 06.02.2003

NEW YORK/CHICAGO (Reuters) - ImClone Systems Inc.'s cancer drug, Erbitux, slows the progression of colon cancer and may even extend life in patients who have exhausted all other options, according to a trial conducted by the company's European partner.

The results, which were presented at the annual meeting of the American Society of Clinical Oncology in Chicago on Sunday, validate at least some of the claims originally made for the drug by Samuel Waksal, ImClone's former chief executive. Waksal was charged with insider trading after the company's marketing application was rejected by U.S. regulators in December 2001, which sent the company's stock into a tailspin.

The results of a trial by Merck KGaA almost exactly mirror the results of ImClone's original trial, which the U.S. regulators considered poorly conducted, making it likely the drug will win approval in the United States quickly, analysts said.

"I think this is now likely to be one of the fastest approvals we have ever seen," said Hemant Schah, an independent analyst who owns shares of ImClone and of its U.S. partner, Bristol-Myers Squibb Co.

The main goals of the trial were to measure tumor shrinkage and the speed with which the disease progressed. The results showed that 23 percent of patients taking Erbitux in combination with chemotherapy saw a 50 percent reduction in tumor size, compared with 11 percent of patients taking Erbitux alone.

Moreover, the median time it took for the disease to progress for patients taking the combination therapy was 4.1 months compared with 1.5 months for those taking Erbitux alone.

Doctors said the latest Erbitux trial differs from the study rebuffed by the FDA in that it enrolled roughly twice as many patients and was more carefully controlled. The FDA has said it would consider reviewing Merck's data as part of a new filing.

The results come less than two weeks before Samuel Waksal is scheduled to be sentenced for insider trading and fraud in a scandal that also tainted Martha Stewart, the TV personality and style-setter who is still under investigation by federal regulators for her sale of nearly 4,000 ImClone shares shortly before the stock plunge.

"I think the news out today will go a very long way toward re-establishing ImClone as a legitimate company and possibly restoring some of its credibility," said Cory Kasimov, an analyst at Ryan Beck & Co.

While the study's goal was not to measure improvement in life expectancy, some intriguing results emerged. The median survival time of patients on the combination therapy was 8.6 months. On Erbitux alone it was 6.9 months. About one third of the 329 patients in both arms of the trial were alive after one year.

There is little reliable data on the average lifespan of a patient from the point he or she is deemed beyond the help of chemotherapy, but most oncologists and analysts agree it is not more than a few months.

"The average lifespan is very short, less than three months," said Dean Lim, staff medical oncologist at City of Hope, a national cancer institute. "These results are significantly better than the historic data we have."

ImClone and Bristol-Myers said it would be premature to draw any conclusions from the life-expectancy data as there has been no formal clinical trial to make such comparisons.

The companies said they plan to use Merck's most recent data to resubmit a marketing application for Erbitux

to the FDA.

"I think it is our intention to try to have a serious conversation with U.S. regulators as quickly as we can," Birkhofer said.

Merck, which is based in Darmstadt, Germany, and is not related to the U.S. drugmaker of the same name, plans to apply for European marketing approval this summer.

"Most people in the medical community who've given this drug believe it works," said Robert Mayer, a Harvard Medical School professor who didn't take part in the trial.
